K071973

510(k) SUMMARY

JUN 20 2008

Submitter's name: Vesticon
2203 N.E. Oregon St.
Portland, OR 97232

Contact name and address: Cathryn Epley, 503-230-0539, fax 503-230-0549

Date summary prepared: March 7, 2008

Device name:

Proprietary name: Epley Omniax™
Common or usual name: Multi-axial chair
Classification name: Vestibular analysis apparatus, LXV, unclassified and Nystagmograph, GWN, 882.1460, Class II.

Legally marketed device for substantial equivalence comparison:

K964325 – VisualEyes from MicroMedical Technologies, Inc.
K863424 – Computer Eye Tracking System/ENG Exam Chair/Table from MicroMedical Technologies, Inc.
K922037 – System 2000 from MicroMedical Technologies, Inc.
K070085 – Balance Rehabilitation Unit from Medicaa, S.A.

Description of the device:

The Epley Omniax is a multi-axial positional chair that includes the chair unit and an operator's pedestal. The chair unit includes the chair itself attached to a frame assembly, seat belts and other restraints, and videonystagmography goggles attached to a computer. The operator's pedestal includes the power distribution system, isolation transformer, and computer with monitor, keyboard, and mouse. The two computers communicate wirelessly to transmit and record the chair movements and the eye movements. The device has a number of safety features, such as emergency stop buttons, override buttons, pinch guards, and manual crank in case of power failure.

The patient is strapped into the Omniax, dons goggles with a camera attached, and the operator selects a series of moves utilizing one or both of the axes. The position of the patient in relation to gravity and any eye movements are shown on the operator's computer and recorded for future viewing. Review of these recordings allows the operator to assess conditions and select appropriate treatment.

Intended use of device:

The Epley Omniax is intended to assist in the diagnosis and treatment of balance disorders and vertigo, including benign paroxysmal positional vertigo.

Technological characteristics:

The Epley Omniax has similarities with several predicate devices. It is used similarly to the combination of VisualEyes and either a Chair-Table or the System 2000. The VisualEyes and Chair-Table combination requires medical personnel to manually manipulate the head while viewing nystagmus. The Omniax uses operator-controlled mechanical means through a software interface. The System 2000 is also operator-controlled through software. The differences are that the Omniax rotates on two axes, while the System 2000 rotates on one axis. All three products record patient data for immediate use or future review. All three products measure spontaneous nystagmus. The Omniax and the combination product measure positional nystagmus and the Omniax and the System 2000 can be used for rotational testing.

Testing conducted:

The Omniax has passed all testing to IEC 60601-1 and IEC 60601-1-2. The goggles have been tested and passed ANSI Z136.1.

Performance testing:

Studies were presented that support the substantial equivalence of the Omniax to VisualEyes used with a table and manual manipulation by medical professionals. The studies performed provide a comparative analysis of the diagnostic and treatment capabilities of the Omniax versus a common standard of care (SOC) method. This SOC method consisted of the combination of videonystagmograph (VNG) goggles and an examination table used by a physician performing manual maneuvers of the patient. 27 subjects completed and were analyzed for the diagnostic study. 37 subjects completed and were analyzed for the treatment study. Both studies reported findings of equivalence to that of the standard of care. In addition, no complications or adverse events were reported in either study.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vesticon
% Ms. Cathryn Epley
President and CEO
2203 Northeast Oregon Street
Portland, Oregon 97232

JUN 20 2008

Re: K071973
Trade/Device Name: Epley Omniax™
Regulation Number: Unclassified
Product Code: LXV, GWN
Dated: June 10, 2008
Received: June 13, 2008

Dear Ms. Epley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1407197 3/5-2

DUPLICATE

XII. Indication for use.

510(k) number: K071973

Device Name: Epley Omniax™

The Epley Omniax is intended to assist in the diagnosis and treatment of balance disorders and vertigo, including benign paroxysmal positional vertigo.

Prescription Use___X___ or (Per 21 CFR 801 subpart D)

Over-The-Counter Use_____ (21 CFR 801 subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE IF NEEDED)

(Concurrence of CDRH, Office of Device Evaluation(ODE)

Neil R Ogden for mkm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071973